Applications of Aerospace Technology in Industry

A TECHNOLOGY TRANSFER PROFILE

PATIENT MONITORING

ACKNOWLEDGEMENTS

This technology transfer profile was prepared for the Technology Utilization Office, National Aeronautics and Space Administration by the Technology Management Group at Abt Associates Inc. under the direction of Warren D. Siemens, Project Supervisor. This report was written by Donald M. Murray.

There is a companion volume available on request from the Technology Utilization Office, NASA, which contains additional information on health care problems, markets for patient monitoring equipment, NASA contributions to all phases of patient monitoring, and reference material for the NASA innovations described. The first and fourth sections of this document are condensations of Chapters 1, 2, and 5 of the Appendix Volume.

Much of the information was gathered with the assistance of NASA in-house and contractor personnel who participated in the development and application of the technology discussed.

APPLICATIONS OF AEROSPACE TECHNOLOGY IN BIOMEDICINE

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PATIENT MONITORING

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PATIENT MONITORING: INTRODUCTION

Improved health care for all members of our society is a major national goal. A combination of a steadily increasing population, rapidly rising medical costs and acute manpower shortages in the biomedical sciences has resulted in a critical situation. In addition to the need for a superior system of health care delivery, there are requirements for the development of more adequate techniques and equipment for the prevention, diagnosis and treatment of disease.

Our most well known health indices are life expectancy and infant mortality. Life expectancy is an expression of the dangers imposed on man by all fatal illnesses throughout an entire life span. Infant mortality is a sensitive indicator of the effectiveness of the health care delivery system. These two indices impose limitations because they do not provide a measure of the state of health or non-fatal illness the population undergoes. However, they do provide us with a guideline for examining the effects of health care.

Over the past half century, life expectancy has gradually increased and the infant mortality rate has decreased in the United States. However, during the past 20 years, life expectancy and infant mortality have remained almost stable in the United States, forcing us to fall behind many foreign countries. In addition, total expenditures for medical care have increased over 130% during the past decade to $63.5 billion in 1969. This increase in medical spending has taken place in an environment of spiraling hospital costs and a growing shortage of trained medical personnel.

One of the main causes for increased spending has been the increase in hospitalization. In 1959 there was a total of 168 million patient days, and in 1969 the yearly total was 200 million. By 1979, patient days are expected to increase by approximately 60%. With the large rise in demand for hospital services and with medical procedures becoming more extensive and complex, a greater number of hospital personnel at a higher unit cost will be required. While the cost of living index has increased by 25% between 1959 and 1969, daily hospital service charges increased by 160%. Hospital personnel costs are a major cause of this dramatic rise. Not only have labor costs increased from 57% of the total cost in 1947 to 66% in 1966, but the number of hospital personnel per 100 patients has increased from 208 in 1959 to 285 in 1969. It is expected that in the 70's increased expenditures on biomedical electronic equipment will relieve hospital personnel of the more routine tasks and will provide more accurate information on a rapid basis.

Biomedical electronic equipment sales have increased from 0.9% of the health care spending in 1959 to 1.3% in 1969. The equipment can be divided into five categories: diagnostic, therapeutic, patient monitoring, electronic data processing, and laboratory equipment. Of these, patient monitoring is the second fastest growing (data processing is first) and in 1969 accounted for 2.5% of the total sales.

Patient monitoring involves the continuous (or frequent, relative to the period of time required for significant change) monitoring of human physiological functions. Monitoring is used in intensive care units, during surgery, in post-operative recovery rooms and even during clinical screening. Although monitoring equipment will never replace the physician's diagnostic capabilities, it does assist him in making a rapid diagnosis by alerting him to a critical situation. Patient monitoring equipment can quickly provide reliable patient information that normally would be difficult to obtain.

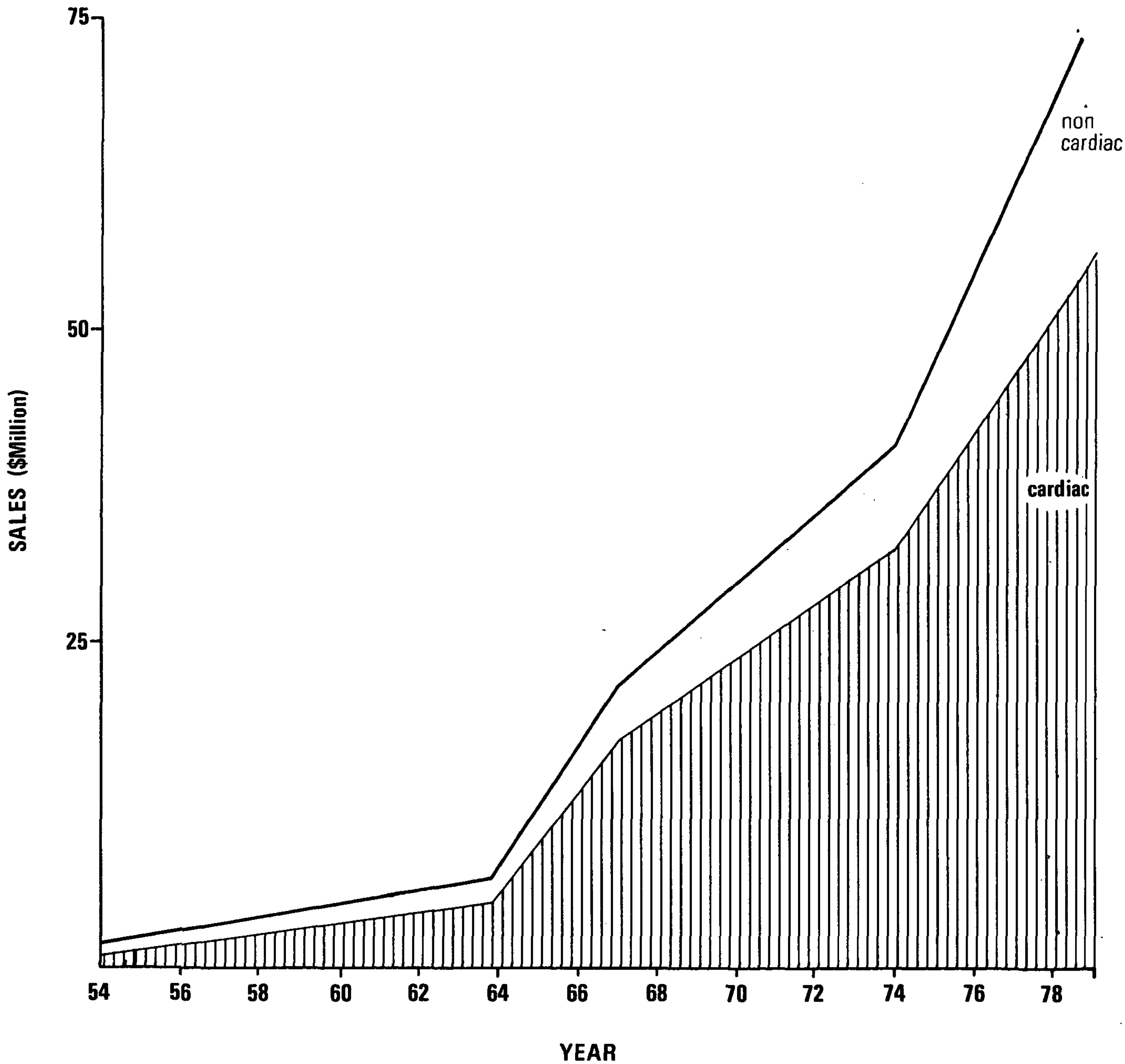
The critically ill patient has a much better chance of survival in an environment where there is continuous care and surveillance. The more seriously ill a patient is, the less deterioration of condition he can tolerate and the sooner corrective action must be taken. Consequently, continuous monitoring is of vital importance: an impossible task with the use of only nursing staff. Equipment which can automatically monitor a patient and alert a nurse or physician in case of emergency is urgently needed. Although the number of hospitals which monitor patients is rapidly growing, there is still a demand for improved and more comprehensive equipment.

Specific requirements for patient monitoring equipment include the need to determine cardiac output, atherosclerotic disorders, precise intracardiac blood pressure, the effect of exercise on the cardiopulmonary system, and respiratory gas analysis. Some of these requirements result in the need for extensive improvements in existing equipment. Other requirements imply that new and innovative equipment must be developed. These improvements and developments may have far-reaching effects on the quality of health care delivered to all patients.

Cardiovascular monitoring equipment has dominated, and will continue to dominate, patient monitoring sales (see figure on next page) due to the fact that continuous monitoring of patients with severe heart trouble can save many lives. Diseases of the cardiovascular system are a primary cause of death in the United States. For example, it has been generally accepted that if ventricular fibrillation can be detected within 1 to 3 minutes after its onset, at least one-third of the patients afflicted can be saved. Such monitoring can only be accomplished by cardiovascular electronic equipment.

NASA is involved in a great deal of innovative and original research and development work. Although this involves many branches of science and engineering, one of the major goals is to understand the effect of the space environment on biological systems -- human systems in particular. This goal results in numerous requirements for understanding human physiological functions under normal and stressed conditions and for monitoring and analyzing the resulting functions. Fulfillment of these requirements has resulted in many benefits to medical researchers and clinicians. NASA has made significant contributions to the field of patient monitoring. The requirements for closely monitoring numerous physiological functions of the astronauts has resulted in many valuable innovations that have been and can be

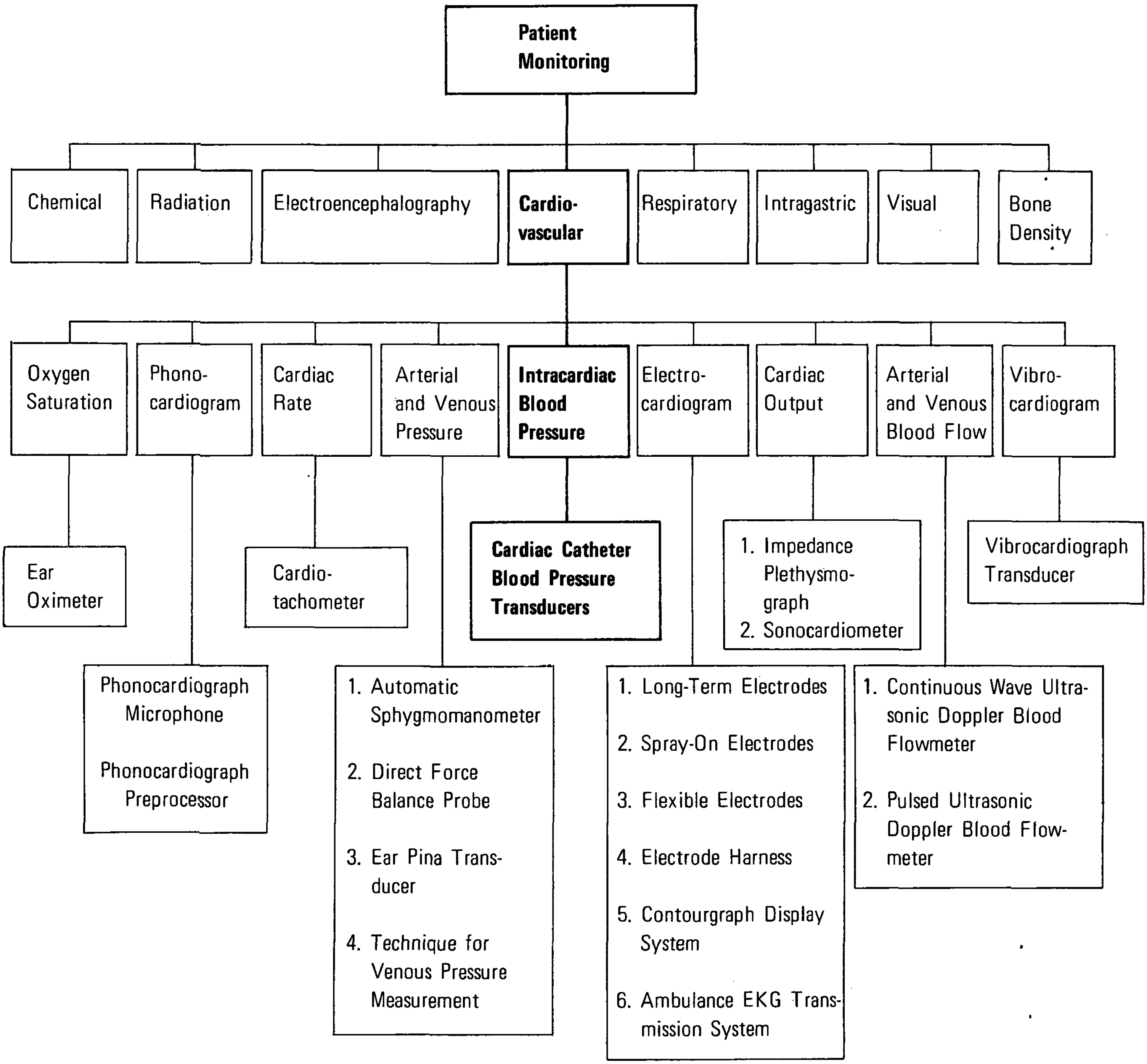
PATIENT MONITORING SALES



Source: Predicast Report, Biomedical Electronics: Patient Care Systems, 1970.

used to improve the monitoring of patients. This report describes many of the NASA contributions to cardiovascular monitoring. In addition, two innovations in intracardiac blood pressure monitoring are discussed in greater depth. The chart on the following page indicates the structure of the report from the general area of patient monitoring down to the detail of cardiac catheter blood pressure transducers.

FOCUS OF THE STUDY



CARDIOVASCULAR MONITORING

The condition of the cardiovascular system is of vital importance. If the flow of blood is stopped, the body will rapidly deteriorate and irreparable brain damage will occur within only four minutes. For these reasons it is extremely important to closely observe a patient whose circulatory system is damaged or weakened. Observation of pulse rate and blood pressure every few minutes is insufficient for a patient in critical condition; these and other parameters must be monitored continuously. The most feasible solution is the use of electronic equipment which can immediately alert a nurse or physician in case of a significant change in heart function. Rapid detection of coronary malfunctions can be the key to saving the lives of many cardiac patients.

Electronic equipment is used to monitor the heart in non-critical situations as well. The electrocardiogram has been used for years to assist physicians in diagnosing heart damage. This type of testing is sometimes called diagnostic monitoring and is used to detect heart damage or irregularities before they become a serious hazard to the patient's health.

In addition to pulse rate and blood pressure, important parameters for cardiovascular monitoring are: electrical signals generated by heart muscles, cardiac output, intracardiac blood pressure, heart sounds, blood flow, and oxygen saturation. New and improved monitoring equipment for detection of these heart functions is constantly being developed.

Electrocardiography (EKG)

One of the most important and well-established methods of monitoring the heart is the technique of recording the heart's electrical activity. The electrocardiogram, as the record is called, can be used to detect heart damage or defects. To perform this task it is necessary to attach electrodes to the chest of the patient. Attaching the electrodes can be time consuming and irritating to the patient because it may involve shaving, cleaning, and abrading the skin to produce good contact, applying irritating electrode jellies and finally gluing on the electrode. Metal electrodes can irritate the skin because of their rigidity, and may be so thick that the patient cannot comfortably lie on them. Most types of electrodes rarely remain securely fastened for more than a day and a half; if the patient does not remain stationary, this time may be further reduced.

Because of the NASA requirement of monitoring the astronaut's EKG waveform, a large variety of electrodes and pastes of advanced quality have been designed. Many types of electrodes were developed at the Manned Spacecraft Center for the purpose of long-term monitoring without irritation or loss of contact. One type of electrode has remained in use for a period of fourteen days during which the subject participated in normal activity. Another electrode has been designed which requires only degreasing of the skin -- an inexpensive and disposable model which saves the time normally spent in cleaning the electrodes for future use.

The well-known spray-on electrodes were developed as a result of a requirement at the NASA Flight Research Center. In order to perform routine monitoring of test pilots, it was necessary to instrument and check out a pilot in less than three minutes. The outcome was a product which could be used to apply a single electrode in 20 seconds. This has been useful for two separate non-NASA applications. First, the spray-on electrodes are valuable for use in EKG clinical screening because they can be applied quickly and removed easily without skin irritation. The electrodes maintain excellent contact for several hours even under active conditions, and can be used by physicians to obtain EKG's from a patient undergoing exercise. The technique of monitoring a patient's EKG during exercise may prove to be very important in detecting heart defects before they become serious.

Secondly, the spray-on electrodes have proved essential for ambulance EKG transmission systems because they may be applied rapidly and reliably even under emergency conditions. The ability of a physician to examine a patient's EKG immediately after a heart attack is extremely important for proper diagnosis and treatment. The transmission system will be discussed in more detail further on in this section.

More recently, flexible electrodes have been developed for extended space mission requirements during which a soft, body conforming, flexible electrode would be valuable. The electrodes consist of silicone rubber loaded with silver-plated particles, which can be molded or cut to fit comfortably over irregular body contours and move with the skin,causing far less irritation than normal electrodes. Because of the comfort of the electrodes, they have excellent possibilities for long-term patient monitoring, especially for infants on whom currently available electrodes are quite large and uncomfortable. In addition to the electrodes, flexible wires have been used as connectors which are comfortable and less likely to break from body movement.

NASA has funded work on a contourograph display system for presentation of EKG data. Contourography is a technique for presenting repetitive analog signals in a highly informative manner. Using this technique, each cycle of a semi-periodic signal is displayed on one of a series of separate horizontal baselines. A major change in the signal stands out from the regular pattern. The EKG may be displayed using the contourography format with the result that each heart beat appears as a series of waveforms. By observing the contourograph, a physician can quickly detect heart irregularities or arrhythmias. The contourograph developed previously by Webb did not display the EKG waveform in its accepted time sequence and the contourogram was generated on a photographic film strip, resulting in a delay for the physician. NASA's device displays the waveform in the correct sequence by using an improved triggering scheme. The waveform is shown on a variable persistance CRT, thus supplying the physician with a real time display of EKG signals.

More than 60% of the deaths from heart attacks occur within an hour after the onset of the attack. Normally the time a patient spends in an ambulance cannot be used for diagnosis or treatment; however, with a system developed as a result of NASA work, it is possible to transmit a patient's EKG from the ambulance to the hospital. This would assist a physician at the hospital in diagnosing a patient before the ambulance has arrived and might even allow the doctor to instruct the ambulance attendant to perform critical treatment. NASA was the pioneer in developing the ambulance EKG transmission system. Use of the spray-on electrodes allows the patient to be connected to the monitor very quickly.

Cardiac Output

NASA has funded work on a four electrode impedance plethysmographic system for monitoring ventricular stroke volume or cardiac output. This device has tremendous potential for clinical use and has already been used to monitor heart transplant patients during the postoperative follow-up period. The system allows a physician to closely monitor the volume of blood passing through the heart without the need for surgically implanted electrodes or transducers. The NASA work resulted in the following improvements:

(1) Only a single channel recording is needed instead of two,

(2) The errors introduced in estimating ventricular ejection time from obscured heart sounds are reduced by the new method of ventricular ejection time detection,

(3) Further reduction in error is achieved by the elimination of the graphical slope extrapolation method and use of the peak magnitude of the rate of change of impedance, and

(4) More comfortable electrodes are available.

The importance of this device is that the failing transplanted heart can be detected at an early stage by monitoring the stroke volume analog. Incipient rejection is indicated by a progressive reduction in stroke volume. Thus, corrective action may be taken before it is too late.

At the Ames Research Center an implantable miniature ultrasonic sonmicrometer has been developed and used to measure the dimensions of the left ventricle and the changes in dimension during a heart beat. The device uses the echoes of high frequency sound waves bounced off the front and rear walls of the heart to electronically determine the heart dimensions. The implantable device has proved feasible, and work on a transcutaneous sonocardiometer is under initial development. The sonocardiometer would be strapped to an astronaut to monitor his cardiac functions and to assess the effects of weightlessness and acceleration. For a patient with heart trouble, this device will be able to provide the means for determining the volume of blood ejected from the heart at each beat, the presence of backward flow indicating valve leakage, and the heart size. Present techniques require catheterization of the heart for which the patient must remain in the hospital.

Phonocardiography

Phonocardiography is the process of obtaining and recording the sounds produced by the heart. This technique provides information different from EKG tests and presents the physician with additional data in the diagnosis of cardiac defects. A microphone has been developed for the detection of the heart sounds. This microphone has a better frequency response as a result of shifting the resonance peak outside the frequency band of interest (20-2,000 Hz). It is small in size and readily adaptable to mass production techniques.

In addition, NASA is developing a heart sound preprocessor which employs methods that give the signal the following advantages:

(1) It is easier to program for computer analysis and requires far less computer storage,

(2) It can be transmitted by standard FM techniques used for other medical signals, and

(3) It is easier to relate to the audible sounds a physician is accustomed to hearing.

The result will be a preprocessor which will enhance the physician's ability to use phonocardiography in detecting heart defects.

Vibrocardiography

Vibrocardiography is the detection of the acceleration of the chest wall resulting from the movement of the heart during the cardiac cycle. It has been shown that the accelerations are strongly related to the stages of contraction, ejection, systole and diastole and that vibrocardiography may produce a record of these as accurately as the method of cardiac catheterization. In order to detect the extremely small accelerations involved, it is necessary to use a very sensitive transducer. NASA has funded the development of a transducer which has excellent frequency response (1.6 to 3,000 Hz, $\pm$ 3db), and a dynamic range of 90 db. This instrument will provide the physician with highly accurate and detailed vibrocardiogram recordings.

Cardiotachometer

A cardiotachometer is a device which monitors and displays heart rate. It is used for a patient in an intensive care unit or during surgery and

and might even be used to monitor a subject undergoing cardiovascular stress analysis. A cardiotachometer with linear beat-to-beat frequency response has been designed by NASA. It has a linear response over the range of 30 to 270 beats per minute and an accuracy of $\pm$ beat per minute. It is capable of continuously displaying the heart rate with a beat-to-beat indication of rate change rather than an averaged rate change. Previous devices required 15 to 20 seconds to register a change from 60 to 120 beats per minute. In critical situations, this delay may not be tolerable.

Cardiac R-Wave Detection

In order to coordinate a heart assist device with the action of a failing heart, it is necessary to obtain a reliable electrical signal that occurs naturally during the heart's systolic contraction. The R-wave portion of the pronounced QRS complex that occurs at the beginning of the heart's pumping cycle can be used to control a heart-assist pump. Previous R-wave detectors have not been totally satisfactory because they occasionally miss pulses or falsely trigger with resulting erratic pumping. A detector developed by NASA has been found to be extremely reliable and accurate. It has been used in conjunction with a NASA artifical heart controller.

Cardiac Blood Pressure Measurement

In intensive care units or during heart surgery it is frequently necessary to monitor the pressure within a patient's heart. A commonly accepted procedure is to insert a catheter through a vein and into the heart. The catheter may either be filled with a fluid and have a transducer at the end (external to the patient's body) to sense the pressure changes transmitted by the fluid, or the catheter may have a transducer at the tip which is inserted into the heart. Catheters with tip transducers are potentially superior because they sense the pressure directly. However, the tip transducers available are relatively large in size, increasing the chances of damage or obstruction to the vein. NASA has been responsible for the development of two different types of transducers for the use on tips of catheters. They are much smaller in size than any presently manufactured (.04 and .02 inches instead of the commercially available .08 inches). In addition, they have better frequency responses which are valuable in obtaining accurate pulse wave forms and possess lower power requirements. The result is that the transducers are highly safe, reliable, and capable of accurately detecting the pulse wave form.

Indirect Blood Pressure Measurement

Blood pressure measurement is probably the diagnostic technique most frequently used by physicians today. The standard instrument is called a sphygmomanometer, and must be used by an experienced nurse or doctor. NASA has been extensively involved in blood pressure monitoring.

One of the earliest devices was an automatic sphygmomanometer, used on the Mercury and Gemini flights. It consisted of an automatically inflating occluding cuff with gas pressure source, gas pressure regulator and valve, transducer for cuff pressure, and a microphone to detect the Korotkoff sounds. The device has been used clinically and was found to be more accurate than the standard manual clinical method.

Another technique employs a transducer as a direct force balance probe to detect the force required to restrain arterial deflection. Although the technique has not been perfected, its feasibility has been demonstrated.

A second type of transducer has been developed for placement on the ear. The device uses a cyclic-occlusion of the ear pina combined with measurement of variations in the opacity of the ear capillary bed to detect blood pressure. The system has been tested and found to be more accurate than the standard method of pressure measurement.

A technique for rapid venous pressure measurement is being investigated. Normally, quantitative venous pressure measurement requires direct entry into a vein. This new method requires only that a patient exhale through a constricted orifice, which causes the pressure to rise in his lungs and the surrounding area including the heart. The pressure measured orally is equal to the venous pressure at heart level. If the oral pressure is increased enough, the blood flow toward the heart in a vein in the arm will cease when the arm is at heart level and the oral pressure is equal to or greater than the venous pressure. A transcutaneous doppler blood flow sensor is used to detect the flow cessation. This method may be of significant value to the clinician in providing rapid non-invasive venous pressure measurement.

Blood Flow

NASA has been funding the development of non-invasive ultrasonic techniques for study of peripheral arterial and venous blood flow. The instruments inject high frequency sound into an artery or vein and detect the phase shift that occurs in the sound which is reflected off of particles in the blood in order to determine the blood's velocity. Electromagnetic flowmeters have been developed by other researchers but they produce only an averaged flow velocity. Prior to NASA research the only ultrasonic flowmeters available gave only qualitative information on flow velocity.

NASA funding has resulted in two innovations. The first was the development of a continuous wave doppler flowmeter capable of sensing direction of flow. The blood reverses direction of flow in the arteries even in normal subjects. Detection of the reversal is advantageous in diagnosing a number of vascular diseases such as arteriovenous fistula, aortic regurgitation, or arteriosclerosis obliterans. Although other directional flowmeters are now available, the first clinically useable one was developed by a NASA researcher.

The second innovation has been the development of a pulsed doppler ultrasonic flowmeter. This device can not only detect the direction of flow, but is also capable of determining the cross sectional flow profile in an artery or vein as well as the internal diameter of the artery or vein. Again the NASA researcher developed the first clinically useable instrument in this country, if not the entire world. Although refinements are needed, the techniques have demonstrated their feasibility and value. The pulsed doppler is capable of producing considerably more information on the condition of the arteries or veins by indicating the location and nature of turbulent blood flow.

The goal of physicians is to obtain a device that can be used to screen patients for the early detection of circulatory diseases. This technique would be extremely valuable in treating a patient before he developed a serious incurable disease. One physician is already using the NASA device to detect (in addition to the diseases already mentioned): thrombophlebitis, occlusion of the internal carotid artery, thoracic outlet syndrome, accurate venous or low blood pressures, condition of arterial grafts, and the condition of a vein or artery during and after catheterization.

In summary, the NASA-developed ultrasonic blood flowmeters show great promise for the future of research and diagnosis of peripheral vascular diseases.

Blood Oxygen Saturation

It is frequently necessary to determine the oxygen saturation in a patient's blood because it is an important indicator of his condition. NASA has sponsored the development of an oximeter which is used on the ear to detect the oxygen content in the blood. The saturation is measured by detecting the percentage of oxygenated hemoglobin in the blood with a photoelectric photometer. Oxygenated and reduced hemoglobin absorb different amounts of light of wavelength 640 millimicrons, but they absorb the same amount of light of wavelength 800 millimicrons. The device therefore uses the difference between the absorption levels to determine the oxygen saturation.

This instrument could be used to monitor a patient during surgery or in an intensive care unit. Continuous measurement could prove invaluable to patients in critical condition.

Cardiovascular Stress Analysis

This is a rapidly growing area of interest among physicians who feel it is important to observe the effect that controlled exercise or stress has upon the cardiovascular system. Stress can reveal a great deal of information about a patient's condition that normal testing cannot show. In addition to the monitoring techniques already discussed, NASA has developed equipment which can be used to measure a controlled amount of stress on a patient. A bicycle-like device called an ergometer has been devised and calibrated in order to monitor the amount of work a patient is performing. In addition, the calibrator makes accurate calibration of any type of ergometer possible so that work rate can be determined and recorded. Therefore the work rate may be duplicated and the effect of exercise may be determined on different ergometers at various locations and under different conditions. Initially developed for studying the effects of weightlessness of astronauts, the ergometer and calibrator show promise as valuable tools for future research and diagnosis of cardiopulmonary diseases.

Another instrument called the lower body negative pressure device was originally designed to test the effect of a weightless condition on the cardiovascular system of an astronaut in space. By subjecting the astronaut's legs and lower body to a partial vacuum, the effect of pooling of the blood in the legs that occurs under gravity is simulated. Regular use by the astronauts may help keep the leg muscles in tone and save them from blood pooling and the resulting fainting spells when they return to earth after a long mission. This device could also be used on a subject to induce a controlled stress, enabling a physician to assess the state of his cardiovascular system. Monitoring a patient's reaction under stress will give early indications of defects that normal testing under rest conditions cannot provide.

In summary, NASA has been responsible for the development of equipment to monitor a large number of cardiovascular parameters: electrocardiographic signals, ventricular stroke volume, heart size, phonocardiographic and vibrocardiographic signals, heart rate, cardiac blood pressure, arterial blood pressure, venous blood pressure, blood flow velocity and volume in arteries and veins, diameter of arteries and veins, and oxygen saturation. Several devices such as the spray-on electrodes, ambulance EKG transmitter, impedance plethysmograph and the R-wave detector have already been used and found to be extremely valuable. Fortunately, NASA is continuing its pioneering work in cardiovascular monitoring and we can look forward to such developments as improved cardiac catheters and the use of ultrasonics in the detection of cardiovascular disease.

CARDIAC CATHETER BLOOD PRESSURE TRANSDUCERS: NASA CONTRIBUTIONS

Cardiac catheters have been used to determine blood pressure within the heart for approximately 30 years. NASA has developed transducers for pressure measurement which are highly sophisticated and compare favorably with products commercially available. Their small diameters make them safe to use on small arteries and veins, their low voltage requirements decrease the chance of shock, and their frequency characteristics enable them to produce very accurate pressure waveforms. It should be emphasized that NASA did not fund work on these devices for the purpose of developing transducers for blood pressure measurement. Rather, these devices were originally designed for use in wind tunnels and other aerospace research; their application to blood pressure measurement is a direct spin-off resulting from NASA research.

NASA has funded the development of two separate pressure transducers, one at the Ames Research Center and one at the Electronics Research Center (ERC)*. These devices were clearly superior to commercially available instruments at the time they were developed. Both devices are presently undergoing initial production and are in competition with the other transducers marketed. Historically, many of the leading transducer products which have been commercially available were those manufactured by Statham Instruments, Inc. Although there have been many other companies engaged in production, Statham appears to have led the field since the beginning. Consequently, primarily Statham products have been used as the guidelines for comparison. This decision was made on the basis of other known available products and recommendations by users.

The Use of Cardiac Catheter Blood Pressure Transducers

It is frequently important to monitor the blood pressure directly within the heart to obtain information on its condition. Direct measurement within a vein or artery may be insufficient because the pulse wave is altered considerably in travelling from the heart. The necessity for monitoring the pressure may arise as a clinical test, in the operating room during surgery, in the post-operative recovery room, or in coronary or intensive care units. Monitoring assists the physician in determining the state of cardiovascular defects, damage, or recovery.

The process of performing blood pressure measurements within the heart is called cardiac catheterization. The most common type is right heart catheterization which involves the insertion of the catheter into an antecubital or femoral vein. After insertion, the catheter is

*The Electronics Research Center has been terminated by NASA and the facilities are now used by the Transportation Systems Center of the Department of Transportation.

advanced through the vein into the superior vena cava and the right atrium. It may then be manipulated into the right ventricle and pulmonary artery, into the inferior vena cava, or into the coronary sinus. The catheter may be left inserted from a matter of minutes to as long as a week.

Left heart catheterization is performed less frequently because it normally requires that the wall of the heart be punctured. This is a more difficult procedure and involves substantially more risk for the patient.

There are basically two types of catheter systems for cardiac blood pressure measurement. The first type is a fluid-filled tube that has a thin membrane at the tip which is inserted into the heart during use. On the opposite end of the tube there is a transducer which remains external to the patient's body. The pressure changes in the heart are transmitted through the membrane and fluid to the transducer. The second type of system is a catheter tip transducer. In this case a very small transducer is situated on the tip of the catheter. The catheter itself consists of current carrying wires that are covered within a thin layer of plastic. The catheter tip transducers are potentially capable of more accurate measurements because the pressure is sensed directly at the transducer rather than at the end of a fluid-filled column. In recent years, several miniature tip transducers have become commercially available. However, a vast majority of the catheter-transducer systems in use are of the first variety, a catheter with an external transducer. This particular device has found wide acceptance with hospitals and physicians because they prefer equipment which has been proven effective over time. This is evidenced by the fact that one basic transducer introduced to the market eight to ten years ago still enjoys considerable use.

Although the fluid-filled catheters are satisfactory, there is much room for improvement. Intracardiac blood pressure is composed of:

(1) variations of low frequency and high amplitude which constitute the normally recorded pressure curves, and

(2) variations of high frequency and low amplitude. They constitute the sounds and murmurs that modulate the pressure curves. The sounds can reach frequencies of 10 KHz and cannot be transmitted through the fluid-filled catheters without considerable attenuation. Catheter tip transducers have the advantage that they can pick up the high frequency sounds. Most such transducers detect frequencies up to 1 or 2 KHz, whereas the fluid-filled systems can only monitor up to about 50-60 Hz.

The high frequency sounds are those recorded in phonocardiograms. The phonocardiogram is usually made by placing a microphone on the chest above the heart; the detected sounds being used to diagnose heart problems. A high frequency response catheter tip transducer has the potential to produce far better phonocardiograms because the sound does not have to travel through the chest. In addition, the transducer may be manipulated to pinpoint the location of a defect and then by using x-rays its exact position in the heart may be specified. The tip transducer may, therefore, be used to diagnose many heart diseases or defects which the fluid-filled catheter cannot. Some of these diseases are: small patent ductus arteriosus, pure mitral stenosis, interventricular septal defect, mitral valve disease, moderate mitral stenosis, slight mitral regurgitation, moderate valvular aortic stenosis, variations of a systolic murmur of mitral insufficiency in the left atrium, aortic insufficiency associated with the valvular aortic stenosis, valvular aortic stenosis associated with mitral stenosis, and subvalvular aortic stenosis-diaphragmatic type and muscular type. It must be noted that catheterization involves higher risks and cost than a standard phonocardiogram and would not normally be used. However, in cases where catheterization is required, the ability to obtain a phonocardiogram with a catheter tip transducer may greatly enhance the physician's ability to diagnose.

Another disadvantage of the fluid-filled catheter is that there is a delay between the heart beat and the transducer detection because of the fluid medium, making it difficult to coordinate the pressure waves with the EKG signals.

One final disadvantage of the fluid-filled catheters is that they are highly subject to motion artifact such as patient movement. Occasionally even the contractions of the heart itself will introduce noise into the transducer.

Most hospitals perform cardiac catheterization on a routine basis. It is a very important technique for monitoring the condition of a patient's heart. In addition to the frequency response and other factors affecting the accurate representation of the pulse wave form, doctors are concerned about the risk involved in catheterization. One major concern is the possibility of electrical shock to the patient. If the electronic equipment short circuits and delivers a shock to the patient through the tip of the catheter in his heart, the result could be fatal. A current as low as 100 microamperes travelling through the heart can cause ventricular fibrillation. Consequently, decreasing the chance of shock is extremely important.

One other factor that must be considered is the size of the catheter (or tip transducer). Use of a large catheter can obstruct a vein or cause venospasm. This is a particular problem in infants because of the small size of their veins. If a fluid-filled catheter is used, then a tradeoff must be made because smaller catheters produce lower frequency responses.

NASA Contributions

NASA researchers have developed two different types of transducers which are being used as catheter tip transducers. The table on page 18 contains the specifications on all of the transducers. The following are brief definitions of the parameters:

Diameter. Diameter of catheter tip (smaller tips are better).

Resolution. The smallest change in pressure that can be measured - (smaller is better).

Natural Frequency. The frequency at which the transducer has peak amplitude out/amplitude in (higher is better).

Frequency Response. The number given is the highest frequency the transducer can reasonably reproduce (higher is better).

Non-Linearity and Hysteresis. Closeness of calibration curve to a specified straight line (smaller is better).

Thermal Zero Shift. Change in output due to temperature effects only (smaller is better).

Rated Excitation Voltage. Voltage supplied to transducer (smaller is better).

Pressure Range. Range of pressures for which non-linearity specification holds true (larger range may be an asset depending on usage).

Maximum Allowable Pressure. The largest pressure the transducer can withstand without damage (larger is better).

Information that is not available from the manufacturers is marked on the table as "no specs."

The first NASA transducer was a capacitance diaphragm-type developed at Ames Research Center as a result of requirements for wind tunnel testing. At the time of development, this tip transducer was smaller in diameter than any others available (.04 instead of .065 inches). It also had a higher frequency response (somewhere between 2 and 10 KHz instead of 2 KHz) and a smaller power requirement (4 volts instead of 7.5 volts) than the commercial product. The Ames transducer is superior to the Statham P866 in all but thermal zero shift and maximum allowable pressure. However, these two differences are really minor since the thermal zero shift is actually quite small and a maximum pressure of 600 mm Hg is really sufficient. The size of the Ames transducer will enable it to be used without fear of venous damage, even on infants. Its high frequency response will produce accurate pressure waves and allow it to be used for phonocardiography, and its smaller power requirements make it potentially safer.

A miniature electromechanical tunnel diode transducer developed at ERC has also been used as a catheter tip transducer. Its specifications are even more impressive than those of the Ames transducer. It is only .02 inches in diameter, one third the size of the smallest commercially available device. Its frequency response (greater than 5,000, possibly as high as 100,000) is much greater than the response of any other tip

CARDIAC CATHETER BLOOD PRESSURE TRANSDUCERS

Parameters	Statham P23Db 1955	Angelakos and Micro Systems Inc. 1963	Statham SF 1 1964	Statham P866 1969	NASA-AMES 1967 Smith, Kline Inc. Initial Production - 1970	NASA ERC 1969 Device Research, Inc. Production: Early 1971 TD-1 (Arterial)	TD-2-V (Venous)
Diameter (Inches)	.09	.09	.083	.065	.04	.02 - .05	.02 - .05
Resolution (mm Hg)	no specs.	no specs.	no specs.	no specs.	.4	Less than 1	.1
Natural Frequency (Hz)	60	8,000	4,500	7,500	82,000	Much greater than 5,000	Much greater than 5,000
Frequency Response (Hz) (In fluid)	60	2,000	Between 750 - 1000	2,000	Between 2000 & 10,000	Greater than 5,000	Greater than 5,000
Non-Linearity and Hysteresis	.7% of full scale	±1% of full scale	2% of full scale	±1% of full scale	1% of full scale	±2% of full scale	±2% of full scale
Thermal Zero Shift (Percent)	no specs.	± .42 mm Hg/°F	no specs.	± .375 mm Hg/°F	.25 mm Hg/°F	.042 mm Hg/°F	.014 mm Hg/°F
Rated Excitation Voltage	7.5 V	6 V DC	7.5 V DC or AC rms	7.5 V DC or AC rms	4 V AC rms	.08V DC	.08V DC
Pressure Range (mm Hg)	-50 to +300	0 to 250	-30 to 300	0 to 3,000	0 to 300	0 to 300	-10 to +25
Maximum Allowable Pressure (mm Hg)	5,000	380	500	900	600	900	250

transducer. These two factors, size and frequency response, will probably make this transducer extremely valuable for phonocardiography because it can detect such high frequency murmurs with such pinpoint type accuracy. There is no other instrument available which can begin to compare with this transducer.

Most impressive of all, however, are the minute power requirements for the ERC transducer. It uses less than .1 volts, 1/40th of the amount of the Ames transducer. This fact will make the ERC instrument extremely safe because the electronic circuitry will not be capable of producing nearly as large a shock as the normal transducer circuitry.

The fine resolution should be noted also, but it is difficult to evaluate because the resolution was unknown on all but one other transducer. The non-linearity and hysteresis may seem somewhat large. However, the value given is the upper bound; an accurate determination had not been made at the time of this report.

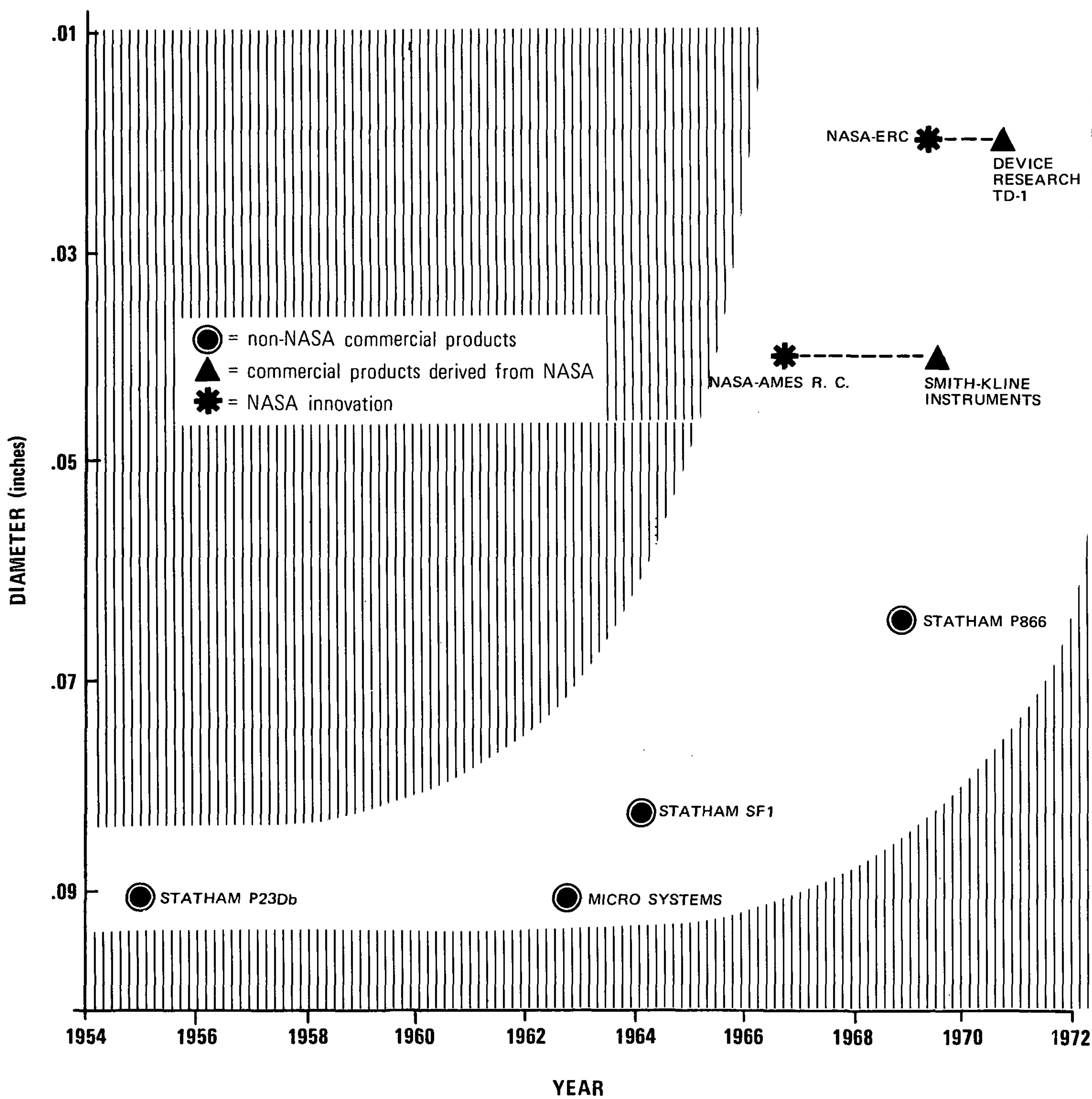
As shown in the table, the ERC transducer has resulted in two slightly different transducers, one for arterial pressure and one for venous pressure measurement. The devices are basically the same and differ only in the pressure range used, resolution, thermal zero shift, and maximum allowable pressure.

The standard Device Research models, TD-1 and TD-2-V, are both made with a diameter of .05 inches at a price substantially lower than the cost of the competitive products. However, upon request, both transducers can be built with a .02 inch diameter at a total cost no higher than that of the other commercially available products.

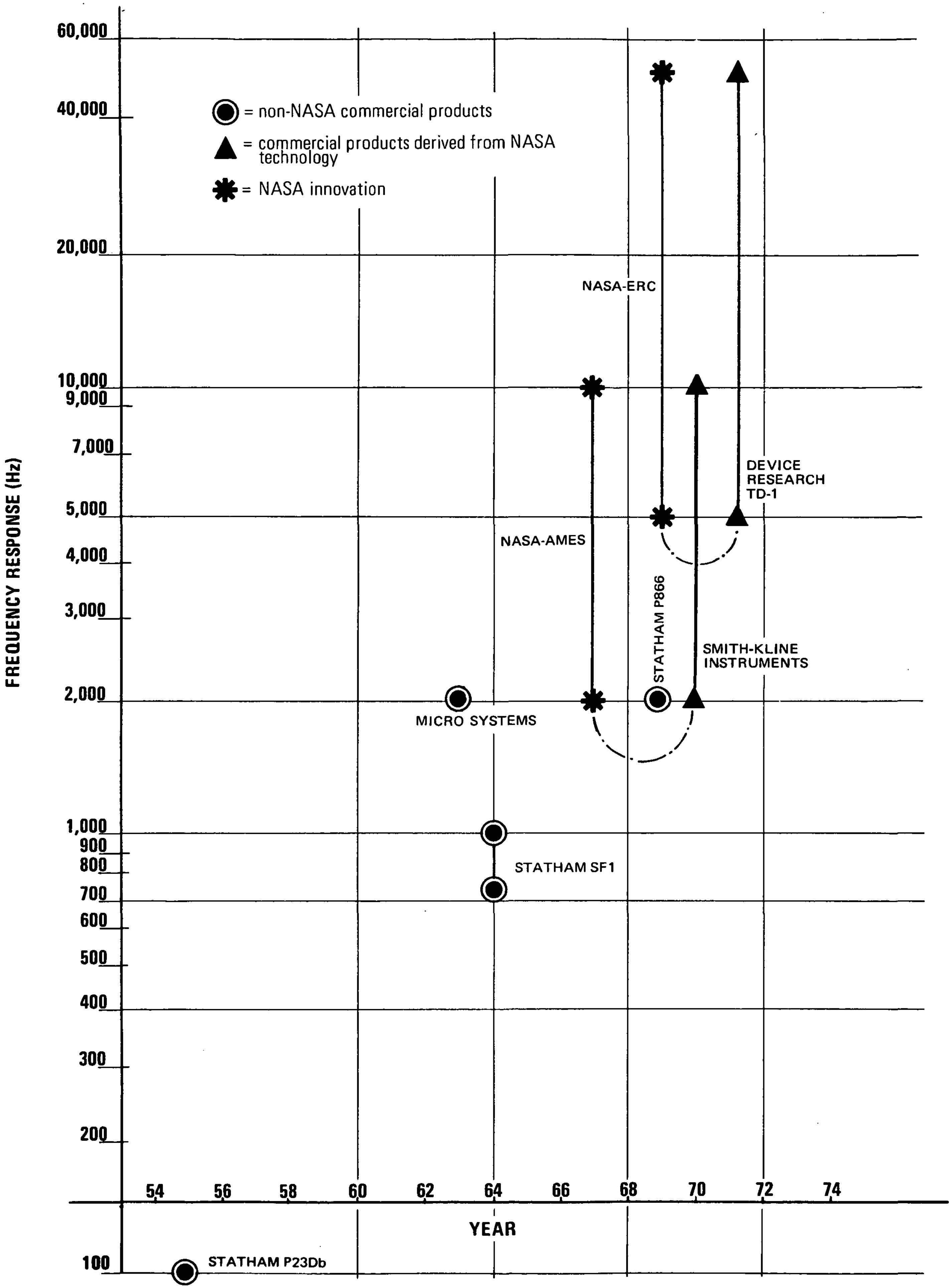
The diameter, frequency response, and rated excitation voltage are plotted in the three graphical displays. These displays indicate the effect NASA has had on the advancement of cardiac catheter tip transducers. The horizontal axis represents the time span in years from 1955 to 1971. The vertical axis represents diameter, frequency response, and rated excitation voltage, respectively, for the three displays. These three parameters are plotted for each of the six basic transducers given in the table. (The TD-1 and TD-2-V are plotted as the same points.) For the transducers which have their frequency response given as a range in the table, the frequency response is plotted as a line rather than a point on the display. In addition to the points which have been plotted according to the table, the graphs also contain points indicating the year that the NASA innovation occurred. For example, on the diameter display, the ERC transducer is plotted at .02 inches in 1971 as the date of commercialization and at .02 inches and 1969 as the date of innovation. The distance between the two points indicates the time lag between invention of the device and its commercial availability.

For the Ames transducer, the time is about three years; for the ERC transducer -- slightly more than one year. The reason for this discrepancy is that there have been production problems with the Ames device, whereas the ERC transducer appears to be advancing quite smoothly.

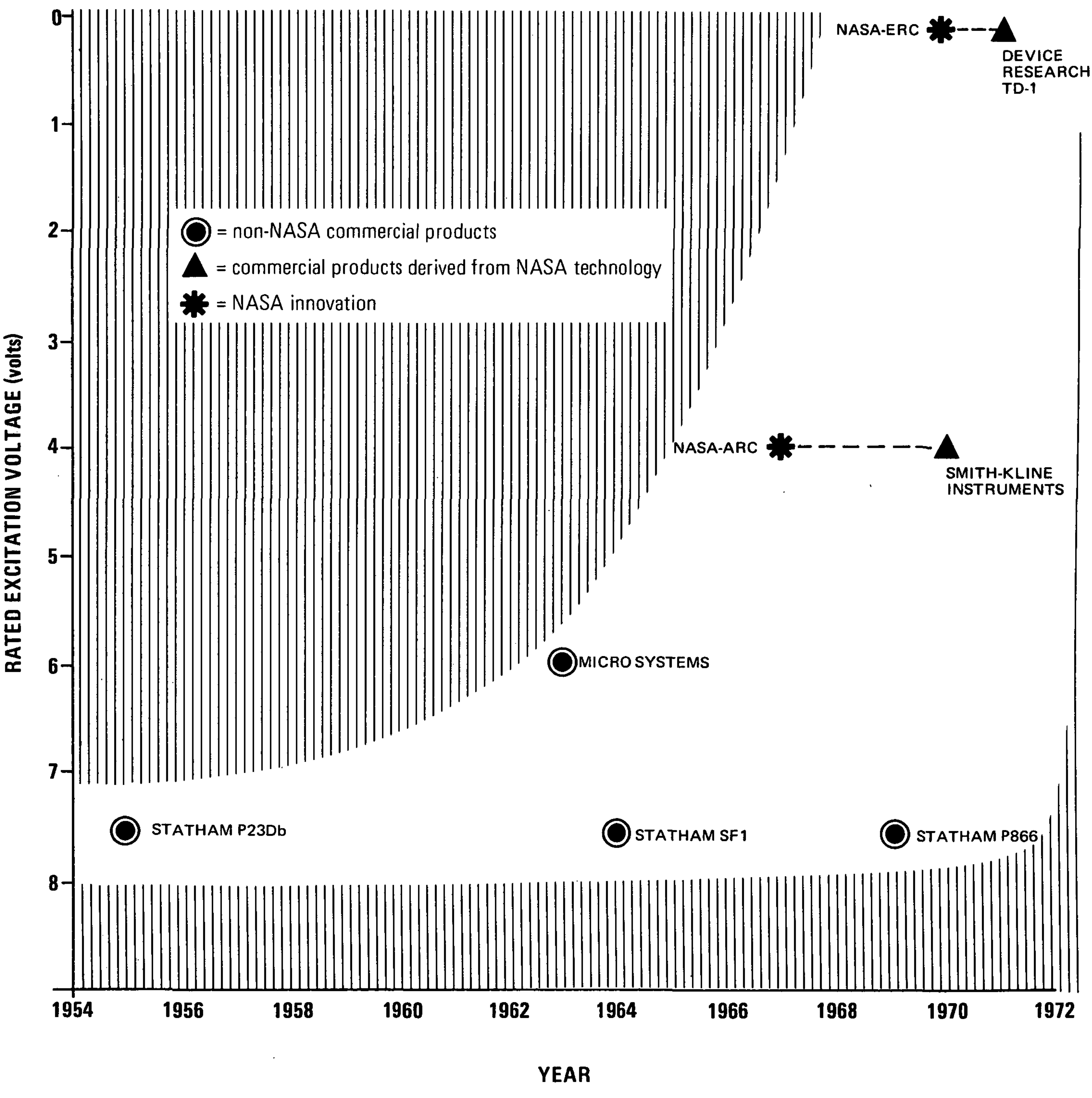
DIAMETER OF CATHETER TIPS



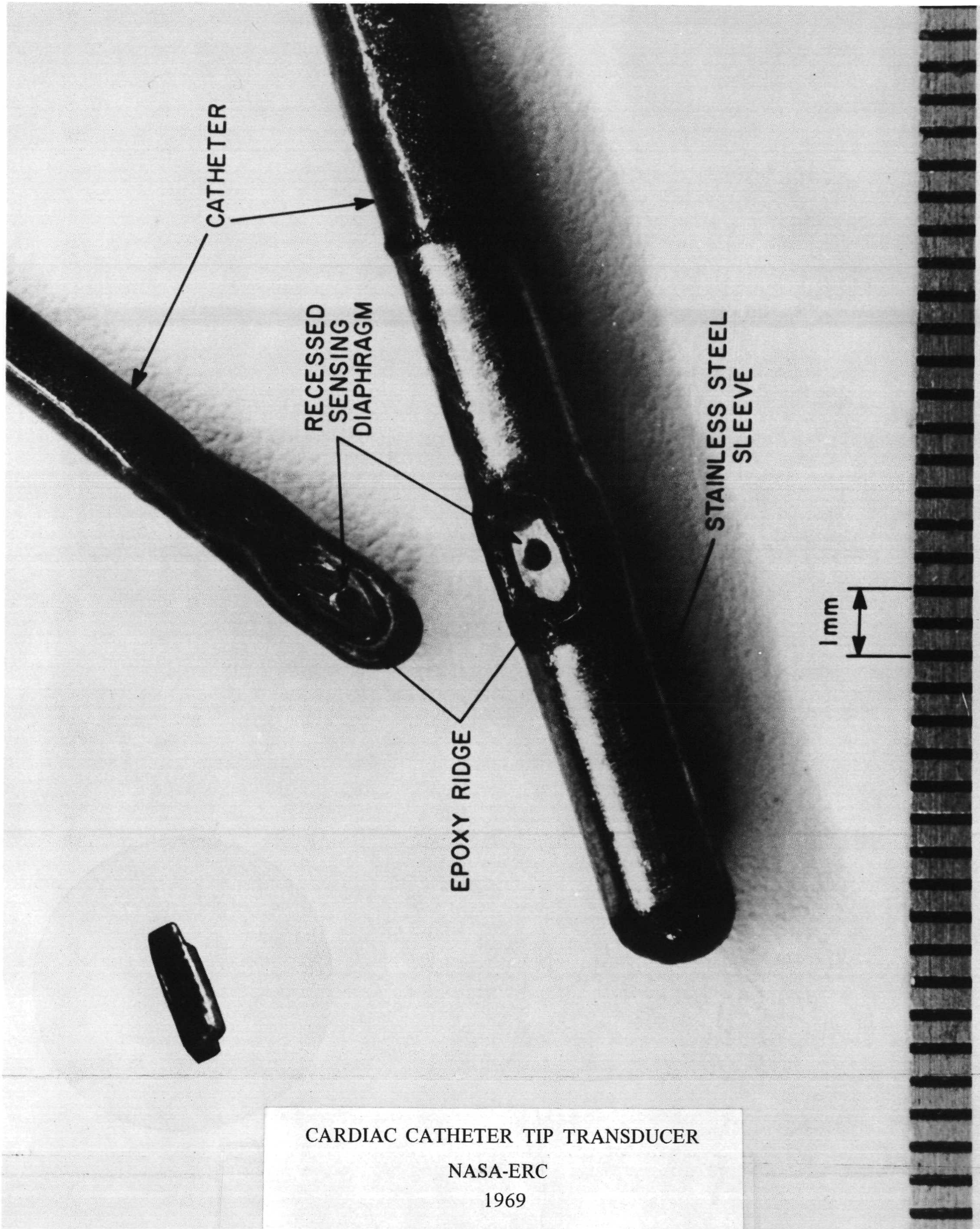
FREQUENCY RESPONSE OF TRANSDUCERS



RATED EXCITATION VOLTAGE



In summary, NASA has made two very impressive contributions to instrumentation for intracardiac blood pressure monitoring. The transducers have significantly advanced the state-of-the-art, especially the instrument developed at ERC which is a substantial innovation. Cardiac catheterization is a very common and important method of monitoring in hospitals. Increased safety and precision are improvements that are vital to the health of every patient who undergoes catheterization. It is difficult to estimate the exact benefit, but lives may be saved as a result of the NASA contributions.



CARDIAC CATHETER TIP TRANSDUCER

NASA-ERC

1969

TECHNOLOGY TRANSFER IN PATIENT MONITORING

The purpose of this section is to present a brief overview of the process of NASA technology transfer as it relates to patient monitoring. A transfer is defined as the adoption of a NASA technique or instrument to solve a non-NASA problem. There are several ways in which a transfer may occur. First, a firm contracted by NASA to design and construct a piece of equipment may later acquire a license to produce it commercially. A second type of transfer occurs when an individual or manufacturer learns of a device through a journal or other literature and inquires about using it or obtaining a license to produce it. In addition, NASA has endeavored to take an active role in the implementation of transfers. The Technology Utilization Division (TUD) was formed specifically to assist in expeditiously transferring NASA technology to the scientific and industrial community. TUD has engaged in an extensive publications program in order to disseminate information. In the area of biology and medicine, TUD has also established three Biomedical Application Teams whose purpose is to actively engage in the process of technology transfer. These teams are located at the Midwest Research Institute, Research Triangle Institute and Southwest Research Institute. The team members communicate with researchers and clinicians at medical institutions to directly assist in solving biological and medical problems.

The Technology Utilization Division publishes Tech Briefs which announce new technology developed under the space program. The Briefs are circulated among thousands of subscribers. More than 70 Tech Briefs have been published that relate directly to the area of patient monitoring.

There is usually a Technical Support Package available as backup material for the Tech Brief, which can be obtained by contacting the NASA center from which the Tech Brief originated. Well over 2,500 TSP's have been requested for the Briefs related to patient monitoring. More TSP's were requested on biotelemetry equipment than on any other group. This phenomenon can be explained by the fact that NASA has developed extremely sophisticated telemetry systems as a result of the requirements for remote communications and monitoring. However, if only physiological functions are considered, by far the most TSP's were requested in the area of cardiovascular monitoring and analysis. This large number of requests occurred for two reasons: first, there is an urgent need to provide better cardiovascular monitoring of critically ill patients and of patients undergoing clinical screening, and second, NASA has done a great deal of work on cardiovascular monitoring because of the intense interest in understanding and monitoring cardiovascular functions of astronauts performing tasks under weightless and other special conditions.

Questionnaires were sent by the Denver Research Institute to a sample of the TSP requestors. The results of the questionnaires revealed that approximately 50% of the requestors had made valuable use of the information in the TSP. This is additional evidence that NASA technology has benefited the biomedical community.

Bioinstrumentation Tech Briefs and the Number of Requestors for Technical Support Packages

Tech Brief Number	Tech Brief Title	Number of Requestors for TSP's
I. CARDIOVASCULAR MONITORING AND ANALYSIS		
B64-10025	Improved Electrode Gives High-Quality Biological Recordings	11
B64-10258	Digital Cardiometer Computes and Displays Heart-beat Rate	8
B65-10010	Inexpensive, Stable Circuit Measures Heart Rate	10
B65-10142	Auxiliary Circuit Enables Automatic Monitoring of EKG's	4
B65-10143	Digital-Output Cardiotachometer Measures Rapid Changes in Heartbeat Rate	4
B65-10320	Rugged Pressed Disk Electrode Has Low Contact Potential	4
B65-10325	Direct Force-Measuring Transducer Used in Blood Pressure Research	2
B66-10049	Improved Electrode Paste Provides Reliable Measurement of Galvanic Skin Response	4
B66-10088	Gelatin-Coated Electrodes Allow Prolonged Bio-electronic Measurements	7
B66-10118	Integral Skin Electrode for Electrocardiography is Expendible	7
B66-10154	Phonocardiograph System Monitors Heart Sounds	29
B66-10649	Spray-On Electrodes Enable ECG Monitoring of Physically Active Subjects	93
B67-10239	A Phonocardiogram Simulator	89
B67-10475	Blood Pressure Reprogramming Adapter Assists Signal Recording	3
B67-10598	Cardiotachometer with Linear Beat-to-Beat Frequency Response	111
B67-10669	Ultraminiature Manometer-Tipped Cardiac Catheter	151
B68-10144	Cardiac R-Wave Detector	55
B68-10220	New Electrical Impedance Plethysmograph Monitors Cardiac Output	65
B68-10233	Electrocardiograph Transmitted by RF and Telephone Links in Emergency Situations	54
B68-10563	Pressure-Sensitive Bonded Junction Transducers	7
B69-10598	Quick Don-Doff Electrode Pastes	16

Tech Brief Number	Tech Brief Title	Number of Requestors for TSP's
B69-10690	Miniature Backward-Diode Pressure Sensor Features Stability and Low Power Consumption	0
B70-10030	Contourograph Display System for Monitoring Electrocardiograms	8
B70-10420	Ultra-Flexible Biomedical Electrodes and Wires	27
	TOTAL	769
II. RESPIRATORY ANALYSIS		
B64-10259	Pneumotachometer Counts Respiration Rate of Human Subject	7
B65-10369	Respiratory Transfer Valve Has Fail-Safe Feature	3
B68-10188	High- and Low-Pressure Pneumotachometers Measure Respiration Rates Accurately in Adverse Environments	5
B68-10365	Automatic Patient Respiration Failure Detection System with Wireless Transmission	56
B68-10438	Nosepiece Respiration Monitor	15
B69-10319	Miniature Oxygen Resuscitator	5
B70-10402	Improved Photoionization Mass Spectrometer	0
B70-10528	Technique for Analyzing Human Respiratory Process	24
	TOTAL	115
III. ELECTROENCEPHALOGRAPHY		
B66-10536	Helmet System Broadcasts Electroencephalograms of Wearer	129
B70-10110	Electronic Sleep Analyzer	11
	TOTAL	140
IV. CHEMICAL ANALYSIS		
B66-10515	Apparatus Enables Automatic Microanalysis of Body Fluids	45
B67-10245	Automated Urinalysis Technique Determines Concentration of Creatine and Creatinine by Colorimetry	15
	TOTAL	60
V. VISION TESTING		
B68-10206	Infrared Viewing Would Permit Human Iris Response Studies	17
B69-10444	Oculometer for Remote Tracking of Eye Movement	0
	TOTAL	17

Tech Brief Number	Tech Brief Title	Number of Requestors for TSP's
VI. TEMPERATURE TELEMETRY		
B66-10057	Miniature Bioelectronic Device Accurately Measures and Telemeters Temperature	282
	TOTAL	282
VII. BONE DENSITY MEASURE		
B68-10140	Instrumentation for Bone Density Measurement	7
	TOTAL	7
VIII. DOSIMETRY		
B66-10252	Semiconductor Forms Biomedical Radiation Probe	2
B68-10426	Ceric and Ferrous Dosimeters Show Precision for 50-5000 Rad Range	0
	TOTAL	2
IX. BIOTELEMETRY		
B64-10171	Subminiature Biotelemetry Unit Permits Remote Physiological Investigations	292
B66-10624	Miniature Telemetry System Accurately Measures Pressure	157
B68-10065	Multichannel Implantable Telemetry System	195
B69-10117	Remotely-Actuated Biomedical Switch	9
B69-10312	New Passive Telemetry System	11
B70-10079	Telemetry for Impact Acceleration Measurements	7
	TOTAL	671
X. MISCELLANEOUS		
B63-10003	New Low-Level A-C Amplifier Provides Adjustable Noise Cancellation and Automatic Temperature Compensation	10
B65-10079	Photoelectric Sensor Output Controlled by Eyeball Movements	20
B65-10091	Simulator Produces Physiological Waveforms	8
B65-10203	Tiny Biomedical Amplifier Combines High Performance, Low Power Drain	177
B66-10534	Miniature Piezoelectric Triaxial Accelerameter Measures Cranial Accelerations	40

Tech Brief Number	Tech Brief Title	Number of Requestors for TSP's
B66-10549	Miniature Electrometer Preamplifier Effectively Compensates for Input Capacitance	105
B67-10076	Cleanroom Air Sampler Counts, Categorizes, and Records Particle Data	115
B67-10369	Multiple Meter Monitoring Circuits Served by Single Alarm	4
B67-10663	Review of Biological Mechanisms for Application to Instrument Design	50
B68-10131	Automated Patient Monitoring System	51
B68-10174	Low Scatter Lightweight Fission Spectrometer Constructed for Biological Research	0
B69-10088	Microscopes and Computers Combined for Analysis of Chromosomes	0
B69-10224	Two Devices for Analysis of Nystagmus	2
B69-10294	Mass Culture of Photobacteria to Obtain Luciferase	0
B69-10385	Improved Perceptual-Motor Performance Measurement System	7
B69-10720	Biomedical Bulk Data Processing Program	0
B70-10107	Detection and Location of Metal Fragments in the Human Body	19
B70-10348	Electromechanical Hand Incorporates Touch Sensors and Trigger Function	4
B70-10452	Self Testing and Repairing Computer: A Concept	2
B70-10508	Log Amplifier Instrument Measures Physiological Biopotentials Over Wide Dynamic Range	
	TOTAL	614

TOTAL OF ALL REQUESTORS 2677

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